

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

Triad Diagnostics
Sotero Ureto, MD
Maria Puno, MD
Mary Clifton, MD
Petoskey Family Medicine
Larry Alton, DO
Maple Cardiology
and Internal Medicine
Kris Haase, DPM
Petitioners

Smita Bijlani, MD
Maura Bagos, DO
MRP MPN Internal
David Bradlee, DO
Mark Karchon, DO
Family Practice of Cadillac
Great Lakes Orthopedics
George Leach, DO
George Grunberger, MD

v

Case No. 11-837-BC
Docket No. 11-000814-OFIR

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 8th day of January 2013
by R. Kevin Clinton
Commissioner

FINAL DECISION

I. BACKGROUND

This case concerns audits by Blue Cross Blue Shield of Michigan (BCBSM) of 17 of its participating providers (Petitioners). Based on its audit findings, BCBSM sought recovery from Petitioners of \$205,139.91 for the audit period of July 1, 2008 through June 30, 2009. The payments BCBSM sought to recover were for medical tests performed by the Petitioners using a device known as a Brevio NCS Monitor which measures the electrical impulses generated in muscles. The measurements are used to help diagnose disorders such as carpal tunnel syndrome.

BCBSM claims that the tests are experimental or investigational and are, for that reason, not covered benefits for which the Petitioners could receive payment. BCBSM asserts that it had informed all its providers, on several occasions beginning in 2002, that the tests were not covered benefits. The Petitioners argue that BCBSM's notifications did not apply to the tests that were performed. The Petitioners argue that BCBSM should not be permitted to recover payments it had made to the Petitioners for these services.

BCBSM conducted an on-site audit of Petitioner Triad Diagnostics beginning in August 2009. The audit report stated that Triad had performed 986 of the experimental/investigational procedures during the audit period. BCBSM sought a refund of \$104,617.58 from Triad.

For the other Petitioners, BCBSM conducted desk audits. BCBSM concluded that these providers each owed smaller refunds. In total, BCBSM sought \$100,522.33 in refunds from these providers.

A Review and Determination proceeding was held by the Commissioner's designee¹ who concluded that BCBSM was entitled to recover the funds in question. The Commissioner's designee also concluded that BCBSM had not violated section 402 of the Nonprofit Health Care Corporation Reform Act of 1980 (Act 350), MCL 550.1402 in pursuing refunds from the Petitioners.

The findings in the Review and Determination were appealed to the Commissioner by the Petitioners. A contested case hearing was held on July 9, 2012 before an administrative law judge (ALJ) who issued a Proposal for Decision (PFD) on September 28, 2012.

At the hearing, testimony was received from three witnesses. The Petitioners' sole witness was Robert Ross, a physician's assistant and co-owner of Triad Diagnostics. Testifying for BCBSM were Constance Blachut, an audit supervisor, and Dr. Frank Judge, Jr., a neurologist at the University of Michigan who was qualified by the ALJ as an expert witness in neurological medicine. A detailed description of the testimony of each witness appears in the PFD, pages 8-18.

The PFD recommended that the Commissioner rule that BCBSM did not violate Act 350 and that BCBSM be permitted to collect refunds from the Petitioners.

Petitioners filed exceptions to the PFD on October 18, 2012. BCBSM filed its response to the exceptions on October 25, 2012. A hearing transcript, ordered by the Commissioner, was submitted on November 16, 2012.

II. PETITIONERS' EXCEPTIONS

In their exceptions to the PFD, the Petitioners made three arguments:

1. See MCL 550.1404.

- There is no evidence in the record that the Brevio device was used to perform surface electromyography or that BCBSM based its request for refund on that basis.
- While none of BCBSM's audit findings were based on the question of medical necessity, several of the PFD's findings were based, improperly, on an alleged lack of medical necessity.
- BCBSM failed to employ reasonable standards in the investigation of claims. The ALJ improperly placed the burden on the Petitioners to determine whether the Brevio device was approved.

These issues are discussed below.

The Brevio device

The Petitioners argue that there is no evidence that the Brevio device was used to perform surface electromyography or that BCBSM based its request for refund on that basis. Petitioners then assert that it was error for the ALJ to conclude that BCBSM had acted reasonably in demanding refunds from the Petitioners. The Petitioners' argument is without merit for the following reasons.

There is evidence in that record that the Brevio device was used to perform surface electromyography. The evidence is provided by the Petitioner's own witness, Robert Ross, the owner of Petitioner Triad Diagnostics. During direct examination the following exchange occurred:

- Q. Would you say that the Brevio performs a surface EMG?
A. Yes.

BCBSM based its demand for refunds on two findings which appear in its "Audit Findings & Corrective Action Report." (Respondent Exhibit 1) The report's "primary decision" was that the Petitioners billed for services that are experimental or investigational. The report's "secondary decision" was that "code S3905 is not a contract benefit and is considered investigational by BCBSM."

The BCBSM position that surface electromyography was experimental/investigational was published in its September 1, 2007 medical policy, "Surface Electromyography."

(Respondent Exhibit 6)² The policy defines surface electromyography as “a method used in the evaluation of neuromuscular disorders that uses surface electrodes to evaluate the electrical activity of muscles.” The policy then describes the shortcomings of surface electromyography in comparison to needle electromyography and concludes that surface electromyography is experimental/investigational.

Thus, BCBSM had concluded that all forms of surface electromyography, not just the Brevio testing, were experimental/investigational and not payable. Because the Brevio device only performs surface electromyography, its use in any circumstance would not be covered.

The role of medical necessity

The Petitioners claim that findings in the PFD were based, erroneously, on a conclusion that the tests were not medically necessary. The Petitioners argue this was error because BCBSM did not base its audit findings on a purported lack of medical necessity. Petitioners state that this error appears in findings of fact 5, 6, 7, 10, and 26.

Findings of fact 5, 6, and 7 are simply restatements of provisions in the participation agreements between BCBSM and Petitioners. They include no “findings” regarding medical necessity.

Finding of fact #10, as noted below, is not adopted as part of this Final Decision. No issue of medical necessity is presented by this case. Findings or arguments related to medical necessity are not necessary to the proper resolution of this case.

Finding of fact #26 refers to a portion of the testimony of Dr. Judge in which he states that how a test interpretation is done “is integral to the device’s efficacy as a clinical tool and thus, medical necessity.” This statement is merely an expression of opinion by the witness. It is not a finding of fact and has no bearing on any issue to be resolved in this case.

BCBSM’s audit conduct

The Petitioners argue that the PFD improperly placed on them the duty to determine if the Brevio tests were approved for coverage. The Petitioners note, correctly, that the BCBSM statute, Act 350, imposes on BCBSM the duty to use “reasonable standards” in claims investigation, based upon available information.” (MCL 550.1211a) However, the present

² A subsequent edition of the medical policy adopting the same position was published in July 2008. This edition is included in Respondent Exhibit 6.

dispute does not concern claim investigation. The claims underlying this dispute were paid by BCBSM before its audit began. Rather, this dispute concerns a BCBSM provider audit. The authority to conduct an audit is afforded BCBSM under its provider agreements with the Petitioners. (See Addendum H to the BCBSM Participation Agreement in Respondent Exhibit 4.)

Whenever a provider challenges audit findings in a contested case hearing, the burden of proof initially falls on the provider, who is in a position analogous to a plaintiff in civil litigation. See OFIR hearing rules 3 and 27(2), R 500.2103 and 500.2127(2). In addition, the ALJ, at the commencement of the hearing, explained that the burden of proof rested with the Petitioners. On the record, the Petitioners' attorney indicated he had no objection to that fact. Tr 6.

The ALJ's conclusion that the Petitioner should have sought BCBSM's approval for their use of the Brevio device was not based on which party bore the burden of proof; the conclusion was based on the ALJ's finding that sufficient evidence had been presented that the Brevio device was not approved and that the Petitioners should have understood they were employing a test which was not covered by BCBSM.

The Petitioners also question the methodology BCBSM used in conducting its audit. According to the Petitioners, BCBSM determined which claims it would seek to recover by identifying claims for surface electromyography which were not followed by the use of needle electromyography. The Petitioners claim that this audit approach was flawed.

While the methodology may have been crude, the results of the audit are not in question. BCBSM conducted the audit and discovered that on numerous occasions the Petitioners billed for surface electromyography with the Brevio device using CPT codes 95900, 95903, and 95904 when they should have used code S3905, a code for which BCBSM would have refused to provide coverage. This was the audit's secondary finding. The primary finding was that the Petitioners used a testing methodology – surface electromyography – which BCBSM had long determined to be experimental/investigational. The hearing record establishes the accuracy of BCBSM's audit finding that the Petitioners used the surface electromyography testing procedure. This finding was not dependent on the audit methodology.

The exceptions filed by the Petitioners are found to be without merit.

III. FINDINGS OF FACT AND CONCLUSIONS OF LAW

The findings of fact in the PFD, except as noted below, are consistent with the hearing record and are adopted.

Finding of Fact #10 is not adopted because it is not required to resolve any issue in this case.

The conclusions of law in the PFD are properly grounded in the facts of this case and are soundly reasoned. The PFD is attached and made part of this Final Decision.

IV. ORDER

It is ordered that BCBSM may recover the funds in question from the Petitioners.

A handwritten signature in dark ink, appearing to read "R. Kevin Clinton", is written over a horizontal line.

R. Kevin Clinton
Commissioner

**STATE OF MICHIGAN
MICHIGAN ADMINISTRATIVE HEARING SYSTEM**

IN THE MATTER OF:

Docket No. 11-000814-OFIR

**Triad Diagnostics, et al.,
Petitioners**

Agency No. 11-837-BC

**Agency: Office of Financial & Insurance
Regulation**

v

**Blue Cross Blue Shield of Michigan,
Respondent**

**Case Type: Appeal
Subscriber/Provider**

Filing Type: Appeal

_____/

**Issued and entered
this 28th day of September 2012
by Lauren G. Van Steel
Administrative Law Judge**

PROPOSAL FOR DECISION

PROCEDURAL HISTORY

Appearances: Keith J. Soltis, Attorney at Law, appeared on behalf of Triad Diagnostics, Sotero Ureta, M.D., Maria Puno, M.D., Mary Clifton, M.D., Petoskey Family Medicine, Larry Alton, D.O., Maple Cardiology & Internal Medicine, Kris Haase, D.P.M., George Grunberger, M.D., Smita Bijlani, M.D., Maura Bagos, D.O., MRG MPN Internal, David Bradlee, D.O., Mark Karchon, D.O., Family Practice of Cadillac, Great Lakes Orthopedics and George Leach, D.O., Petitioners. Bryant D. Greene, Attorney at Law, appeared on behalf of Blue Cross Blue Shield of Michigan, Respondent.

This proceeding under the Nonprofit Health Care Corporation Act, 1980 PA 350, as amended, MCL 550.1101 *et seq.* (hereafter "Nonprofit Act") commenced in the Michigan Administrative Hearing System with the issuance of a notice of hearing on August 5, 2011, which scheduled a contested case hearing for September 21, 2011. The notice of hearing was issued pursuant to a July 27, 2011 request for hearing and Order Referring Complaint for Hearing and Order to Respond by Special Deputy Commissioner of the Office of Financial and Insurance Regulation.

The Complaint references allegations set forth in the Petitioners' Request for Contested Case Hearing, dated July 19, 2011, by which Petitioners seek reversal of the Review and Determination issued by the Commissioner's Designee on May 25, 2011. The

Commissioner's Designee concluded that Respondent had not violated any of the provisions of Section 402 of the Nonprofit Act when it pursued refunds from Petitioners in the total amount of \$205,139.91, following post-payment audits.

On August 23, 2011, the parties filed a stipulation to adjourn the September 21, 2011 hearing date and to schedule a telephone prehearing conference. On August 25, 2011, the undersigned issued an Order Granting Adjournment and Scheduling Telephone Prehearing Conference. On August 30, 2011, Respondent filed its Answer to Petitioners' Request for Contested Case Hearing.

On September 21, 2011, the undersigned held a prehearing conference with the parties' attorneys by telephone as scheduled. On September 23, 2011, the undersigned issued an Order Following Prehearing Conference and scheduled the hearing for December 5, 2011. On November 4, 2011, Petitioners filed a Witness List, Exhibit List and Initial Discovery Requests from Blue Cross Blue Shield of Michigan.

On November 14, 2011, Petitioners filed a Motion for Summary Judgment. On November 18, 2011, the undersigned issued an Order Adjourning Hearing and Scheduling Motion Hearing. On November 21, 2011, Respondent filed a Response to Petitioners' Motion for Summary Judgment. On November 28, 2011, Petitioners filed a request that the motion hearing be held by telephone, which request was granted without objection.

On November 14, 2011, the motion hearing was held by telephone as scheduled, and Petitioners' Motion for Summary Judgment was denied on the record. On December 13, 2011, the undersigned issued an Order Denying Petitioners' Motion for Summary Judgment and Scheduling Hearing. The Order scheduled hearing for February 14, 2012. On February 7, 2012, Respondent filed a request to adjourn the hearing date. On February 14, 2012, the undersigned issued an Order Granting Adjournment, rescheduling the hearing to April 18, 2012.

On March 7, 2012, the parties filed a stipulation to adjourn the hearing date. On March 22, 2012, the undersigned issued an Order Granting Adjournment, rescheduling the hearing to June 14, 2012. On April 26, 2012, the parties filed a stipulation to adjourn the hearing date. On May 2, 2012, the undersigned issued an Order Granting Adjournment, rescheduling the hearing date to July 9, 2012.

On July 3, 2012, Respondent filed amended witness and exhibit lists. On July 6, 2012, Respondent filed an additional amendment to its exhibit list. On July 6, 2012, Petitioners filed an amended exhibit list. On July 6, 2012, Respondent filed another amended exhibit list.

On July 9, 2012, the hearing was held as scheduled. Petitioners called Robert Ross, P.A., and Kevin Mayrand to testify as witnesses. Respondent called Constance Blachut and Frank Judge, M.D. to testify as witnesses.

Petitioners offered the following exhibits, which were admitted into the record as evidence:

1. Petitioners' Exhibit No. 1 is a copy of an article, "Understanding the Difference Between Traditional and Automated Nerve Conduction Study Devices," Neurotron Medical Inc., dated November 6, 2009.
2. Petitioners' Exhibit No. 2 is a copy of compiled correspondence including audit results, managerial level conference results, and accompanying documents for each Petitioner.
3. Petitioners' Exhibit No. 3 is a copy of Respondent's publication to providers, *The Record*, dated July 2007.
4. (Petitioners did not offer an Exhibit No. 4.)
5. Petitioners' Exhibit No. 5 is a copy of "Recommended Policy for Electrodiagnostic Medicine" from the American Association of Neuromuscular & Electrodiagnostic Medicine, last updated 2004; "Practice Parameter: Electrodiagnostic Studies in Carpal Tunnel Syndrome" from the American Academy of Neurology, dated 2002; and "Carpal Tunnel Syndrome" from the Physicians' Information and Education Resource, dated 2009.
6. Petitioners' Exhibit No. 6 is a copy of the "Practitioner Traditional Participation Agreement", Blue Cross Blue Shield of Michigan, dated July 2009.
7. Petitioners' Exhibit No. 7 is a list of published clinical studies regarding "NeuMed's core NCV technology used in the original Nervepace models followed by the Brevio".
8. Petitioners' Exhibit No. 8 is a copy of the NeuroMax 640/1000 User Manual.
9. Petitioners' Exhibit No. 9 is a copy of E-mail messages with BCBSM concerning approved machines, dated July 8, 2010.
10. Petitioners' Exhibit No. 10 is a copy of a Brevio® Version 4.0 User Manual, dated 2008.
11. Petitioners' Exhibit No. 11 is a copy of the Curriculum Vitae of Richard Ross, P.A.
12. Petitioners' Exhibit No. 12 is an XL-Tek study, dated July 7, 2012.

13. Petitioners' Exhibit No. 13 is a Brevio® study, dated July 7, 2012.
14. Petitioners' Exhibit No. 14 is an XL-Tek study, dated July 9, 2012.
15. Petitioners' Exhibit No. 15 is a Brevio® study, dated July 9, 2012.

Respondent offered the following exhibits, which were admitted into the record as evidence:

1. Respondent's Exhibit No. 1 is a copy of a BCBSM Audit File (Audit ID 200901856).
2. Respondent's Exhibit No. 2 is a copy of "General Limitations and Exclusions" documentation guidelines, effective December 1, 2004.
3. Respondent's Exhibit No. 3 is a copy of *The Record* articles from March 2002, July 2007 and September 2008.
4. Respondent's Exhibit No. 4 is a copy of an undated "Physician and Professional Provider Participation Agreement", with Addenda A through I.
5. Respondent's Exhibit No. 5 is a copy of a review by Frank Judge, M.D., dated March 24, 2011.
6. Respondent's Exhibit No. 6 is a copy of the BCBSM Medical Policy on "Surface Electromyography", last updated July 1, 2008.
7. Respondent's Exhibit No. 7 is a copy of the Brevio User Manual, dated 2006.
8. Respondent's Exhibit No. 8 is a copy of the State of Washington Department of Labor and Industries provider bulletin: 07-06.
9. Respondent's Exhibit No. 9 is a copy of the Review and Determination by Susan M. Scarane, Commissioner's Designee, dated May 25, 2011.
10. (Respondent did not offer an Exhibit No. 10.)
11. (Respondent did not offer an Exhibit No. 11.)
12. Respondent's Exhibit No. 12 is a copy of the American Association of Neuromuscular & Electrodiagnostic Medicine article on "Proper Performance and Interpretation of Electrodiagnostic Studies", dated March 2006.

13. Respondent's Exhibit No. 13 is a copy of medical policy on NCS from competing insurers.

The record was closed at the conclusion of the hearing.

ISSUES AND APPLICABLE LAW

The central issues presented in this matter are:

- 1) Whether Respondent has violated Sections 402(1)(a)-(f) & (l)-(m) of the Nonprofit Act, *supra*, as alleged in the Complaint and Petitioners' Request for Contested Case Hearing; and

- 2) Whether Respondent is entitled to seek refund from Petitioners, totaling \$205,139.91, following post-payment audits.

The applicable statutory sections of the Nonprofit Act provide as follows:

Sec. 402. (1) A health care corporation shall not do any of the following:

- (a) Misrepresent pertinent facts or certificate provisions relating to coverage.

- (b) Fail to acknowledge promptly or to act reasonably and promptly upon communications with respect to a claim arising under a certificate.

- (c) Fail to adopt and implement reasonable standards for the prompt investigation of a claim arising under a certificate.

- (d) Refuse to pay claims without conducting a reasonable investigation based upon the available information.

- (e) Fail to affirm or deny coverage of a claim within a reasonable time after a claim has been received.

- (f) Fail to attempt in good faith to make a prompt, fair, and equitable settlement of a claim for which liability has become reasonably clear.

* * *

- (l) Fail to promptly provide a reasonable explanation of the basis for denial of a claim or for the offer of a compromise settlement.

(m) Fail to promptly settle a claim where liability has become reasonably clear under 1 portion of a certificate in order to influence a settlement under another portion of the certificate. MCL 550.1402(1)(a-f) & (l-m).

Petitioners requested a contested case hearing in accordance with Section 404(6) of the Nonprofit Act, *supra*, which provides:

Sec. 404. (6) If either the health care corporation or a person other than a member disagrees with a determination of the commissioner or his or her designee under this section, the commissioner or his or her designee, if requested to do so by either party, shall proceed to hear the matter as a contested case under the administrative procedures act. MCL 550.1404(6).

The administrative rules on Procedures for Informal Managerial-Level Conferences and Review by Commissioner of Insurance, 1986 AACCS, R 550.101 *et seq.*, state in pertinent part:

Rule 102. (1) A person who believes that a health care corporation has wrongfully refused his or her claim in violation of section 402 or section 403 of Act No. 350 of the Public Acts of 1980, as amended, being S550.1402 or S550.1403 of the Michigan Compiled Laws, or has otherwise violated section 402 or sections 403 of Act No. 350 of the Public Acts of 1980, as amended, shall be entitled to a private informal managerial-level conference with the health care corporation.

* * *

(4) At the time of a refusal to pay a claim, the health care corporation shall provide in writing to the member and, if the claim was made by a provider, to the provider, a clear, concise, and specific explanation of all the reasons for the refusal. This notice shall notify the member or provider of the member's or provider's right to request a private informal managerial-level conference if the member or provider believes the refusal to be in violation of section 402 or section 403 of Act No. 350 of the Public Acts of 1980, as amended, being S550.1402 or S550.1403 of the Michigan Compiled Laws. 1986 AACCS, R550.102(1)&(4). (Emphasis supplied).

Rule 103. (1) Within 10 days of the conclusion of the private informal managerial-level conference, the health care

corporation shall provide all of the following information to the grievant:

- (a) The proposed resolution of the health care corporation.
 - (b) The facts, with supporting documentation, upon which the proposed resolution is based.
 - (c) The specific section or sections of the law, certificate, contract, or other written policy or document upon which the proposed resolution is based.
 - (d) A statement explaining the person's right to appeal the matter to the commissioner within 120 days after receipt of the health care corporation's written statement provided in subrule (2) of this rule.
 - (e) A statement describing the status of the claim involved.
- 1986 AACCS, R 550.103(1).

Rule 104. (2) The grievant may appeal to the commissioner within 120 days of the date the person received the health care corporations' proposed resolution . . . 1986 AACCS, R 550.104(2).

Rule 105. (3) The commissioner or commissioner's designee shall conduct meetings in a manner which allows the disputing parties to present relevant information to substantiate their positions. 1986 AACCS, R 559.105(3). (Emphasis supplied).

Rule 107.(3) The commissioner or the commissioner's designee shall notify the health care corporation and the grievant of the right to request a contested case hearing if a party disagrees with the written decision. 1986 AACCS, R 550.107(3). (Emphasis supplied).

Rule 108. (1) If the decision by the commissioner or the commissioner's designee indicates that the grievant's claim was wrongfully refused in violation of section 402 or section 403 of Act No. 350 of the Public Acts of 1980, as amended, being S550.1402 or S550.1403 of the Michigan Compiled Laws, the wrongfully refused claim shall be paid within 30 days of the date the decision is mailed to the health care corporation.

(2) A claim which is payable to a member shall bear simple interest from a date of 60 days after a satisfactory claim form was received by the health care corporation, at a rate of 12% interest per annum. The interest shall be paid in addition to,

and at the time of payment of the claim. 1986 AACCS, R 550.108.

SUMMARY OF EVIDENCE

The following is a summary of the evidence presented at hearing:

Testimony of Robert R. Ross, P.A.

Robert R. Ross, P.A. was called by Petitioners to testify. Mr. Ross testified that he is a licensed physician's assistant in the state of Michigan. He is the co-owner of Triad Diagnostics, a limited liability corporation in the state of Michigan that is recognized as an independent diagnostic testing facility with Medicare. Triad Diagnostics performs nerve conduction testing for physicians in the physicians' offices and performs ultrasound testing and Doppler evaluations for patients with peripheral arterial disease. Triad Diagnostics works with a large array of different providers (the non-Triad Petitioners), including internal medicine physicians, orthopedic physicians, family practice physicians, endocrinology physicians and podiatrists.

Mr. Ross testified that he received training in a physician's assistant program at the Indiana School of Medicine and graduated in 1977. He then practiced in Michigan in occupational medicine for several years, during which time he performed several nerve conduction evaluations on patients. He also worked for a family practice medicine practitioner, where he gained experience in neurological testing with a physiatrist who came in on Saturdays to perform such testing. He is also a past president of the Michigan Academy of Physician's Assistants. [Pet. Exh. 11].

In 2002, Mr. Ross incorporated Triad Diagnostics with a neurologist. He received special permission from the chair of the Department of Neurology at the University of Michigan to attend the same courses as physician residents. He has received additional training in nerve conduction through a nationally recognized course, the Larry Head Institute, and the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM). He also recently attended a course at the University of Michigan on nerve conduction studies.

Mr. Ross testified that the claim denials at issue relate to the "technical"¹ component for Petitioner Triad Diagnostics, and relate to the "professional component" for the remaining Petitioners who are health care providers.

Mr. Ross stated that physicians would order nerve conduction testing for specific conditions, such as carpal tunnel syndrome, diabetic neuropathy and cervical radiculopathy. If a physician feels that it is necessary, an EMG (electromyography) may be done, in which there is an electrode invasion of the patient's muscle and a needle

¹ Quoted testimony is based solely on the undersigned's review of the audio recording of the hearing; a hearing transcript has not been prepared to date.

inserted into the skin. In most of the studies that Triad Diagnostics has performed, a nerve conduction study was done on top of the skin in order to test nerve conduction flow from one point to another, and the physician did not state that an EMG must be done.

Mr. Ross testified that he has personally trained the Triad Diagnostics technicians who have performed the nerve conduction studies for the provider Petitioners. Mr. Ross conducts a six-week training of technicians that is also submitted to Medicare. The technicians have also had training with a personal trainer from the Larry Head Institute. The technicians always perform tests along with a trained technician until they get a certificate.

Mr. Ross testified that he is familiar with the Brevio® and the XL-Tek nerve conduction devices. The XL-Tek device that he brought to the hearing for demonstration purposes is a nerve conduction machine that sets up with electrode adapters that apply a sticky electrode receptor to the patient's fingers or toes. The stimulator, which is used to stimulate the electrical current, is gauged on the machine. The technician gauges that up to what is called a "super-maximal" stimulation. The electrode is placed on the nerve being tested. The electrode receptors are placed on the fingers or toes which the nerve enervates to. The stimulation button is clicked and the wave shows up on the screen. The technician then turns it up to the super-maximal point, and then that is saved on the machine and later put through a printer for immediate results.

Ms. Ross stated that with the Brevio® device, he is not able to do an EMG. With the XL-Tek and some of the other approved devices, he is able to do an EMG. He can also do just a nerve conduction study alone (without an EMG) with the XL-Tek.

Since the time of the audit, Triad Diagnostics is not continuing to use the Brevio® device. Rather, it is now only using the XL-Tek device that is made by NeuroMax. [Pet. Exh. 8]. With the XL-Tek, Triad Diagnostics is not performing EMGs with all the nerve conduction studies. Mr. Ross did not have to re-train technicians in switching from the Brevio® to the XL-Tek on the physiology or technique of nerve conduction studies, because the functions and tests of both machines are the same.

Mr. Ross testified that he is familiar with the July 2007 article in Respondent's publication, *The Record*, regarding procedure code "S3905". The description for code S3905 does not describe the nerve conduction testing being done on the Brevio®. He would say that the Brevio® performs a surface EMG. The Brevio® performs the nerve conduction studies described in CPT codes 95900, 95903 and 95904. The studies that were performed subject to the audit for Triad Diagnostics and the non-Triad Petitioners were code numbers 95900, 95903 and 95904.

Mr. Ross testified that the Brevio® and XL-Tek devices both have automated features. He stated that there are features of both devices that are computerized. Both devices produce real-time results that are displayed on the monitors. The NC-Stat device does not display real-time results. When Respondent's policy came out in 2008 for code

S3905 related to automated devices, it did not describe the type of testing done by the XL-Tek device. The nerves required to be tested for procedure codes 95900, 95903 and 95904 can be tested on the XL-Tek and the Brevio®. If a supervising physician determines that there is a need to test additional nerves or branches of nerves, the XL-Tek and the Brevio® could do that.

Mr. Ross testified that he has conducted thousands of nerve conduction tests. There is absolutely no difference in how the nerve conduction test is performed between the Brevio® and the other approved devices. There is a complete difference, however, between how the nerve conduction studies are done with the Brevio® and other approved devices, and with the NC-Stat device.

At the hearing, Mr. Ross performed a demonstration of a median nerve conduction test on Kevin Mayrand (who is co-owner of Triad Diagnostics, LLC and president of the company's sales, marketing and development). Mr. Ross first conducted the test using the XL-Tek device and testified as he conducted the demonstration on what was occurring.

Mr. Ross indicated that he first prepped the skin and then applied a "ground electrode" (green wire) on the back of Mr. Mayrand's hand. He placed an "active electrode" (black wire) on the thenar eminence of the hand and a "reference electrode" (red wire) on the thumb. He testified that he did a skin temperature test showing 32°C, which is adequate for the test. He turned on the machine, and selected "median nerve", "motor nerve conduction test" and "left hand". He testified that the screen popped up for real-time studies. He measured 7cm from the mid-point of the thenar eminence muscle and made a small mark of reference. He stated that he applied an electrode gel to the stimulator tips. He set the stimulator at about 15 milliamps and touched it to allow a stimulation of nerves measured at 7cm. He stated that he noticed that it was not enough stimulation, so he increased it to about 23 (milliamps). Mr. Ross testified that the subject's thumb moved when he hit the stimulator button. The latency time was 3.8 and the amplitude was 4.4. He increased it just slightly to "super-maximize" the stimulation of the nerve to 35 (milliamps), to make sure he had collected as much information as possible. It did not change, so it was "super-maximized". He pushed "1" and it was recorded and printed out. Mr. Ross testified that this was a "motor" nerve conduction test that would be classified as CPT "code 95900".

Next, Mr. Ross performed an "F-wave stimulation with the motor" nerve conduction test using the XL-Tek, which he testified would be classified as a CPT "code 95903" (motor nerve with F-wave). He went back to the test memory to the pre-selected "median nerve". It was already selected as a "motor nerve" and then the "F-wave" was pre-selected. He reversed the polarity on the stimulator by turning it upside down. He started out at 35 (milliamps) to stimulate the subject's hand approximately eight times. He used the same reference point of 7cm. It was 3.8 again, and he concurred that was the right amount of electrical impulse to use. He pushed it again for eight stimulations. He then pushed the test menu and that saved it on the screen.

Mr. Ross then performed a "sensory test" on the XL-Tek, which he stated would be classified as CPT "code 95904". He reattached the electrodes to the subject's index finger. The reference electrode was distal and the active electrode was proximal. The measurement was 14 cm. He marked the reference point. The median nerve was already pre-selected, and he skipped back to the sensory nerve. He started at about 10 milliamps of stimulation. He went further to see the wave coming in, to "super-maximalize" the stimulation on the sensory nerve. He pressed #2 for the index finger, which saved it in the machine and could be easily printed for the physician's office record.

Petitioners' Exhibit No. 12 is a printout of the XL-Tek test that Mr. Ross performed on himself the day prior to hearing, which shows the wave and number interpretation.

Next, Mr. Ross set up the Brevio® machine. Mr. Ross testified that he connected the ground electrode first, and then the reference electrode distally on the thumb. He placed the active electrode on the thenar annex of the right hand. He measured the temperature of the hand at 32°C. He turned on the Brevio® and it was already programmed. He hit the mode to put it in the place of "motor." The machine asked him which nerve to label and he labeled it as "median wrist". The machine asked him which side and he labeled it as the "right side". He exited the labeling and was ready to perform the test. At the top, the mode is "motor", "right hand" and "median wrist". Mr. Ross testified that this test would be classified as CPT "code 95900". He applied conduction gel to the stimulator. He measured 7cm from the thenar eminence to the point of conduction. He set his gauge at 10 (milliamps), as he did on the other machine, and moved it up to 20. He moved it up more about 5 (milliamps), and it "super-maximalized" and stayed at 3.4. He saved it, just as he would on the XL-Tek, and was then ready to perform the "F-wave" test.

Mr. Ross testified that he labeled the "F wave". He stated that combined with the "motor" test, this test would be classified as CPT "code 95903". The machine asked him which nerve and side he was going to test. He told the machine to test the "median nerve" and "right side". On the display, the machine stated: "motor", "F-wave", "right hand" and "median wrist". He left the electrode stimulation at the same rate as he did before and reversed the polarity for eight stimulations. He saved the results on the machine.

Mr. Ross testified that he was then performing the "sensory" test, which would be classified as CPT "code 95904". He re-placed his electrodes as he did on the XL-Tek: reference distal and active proximal. He cleansed the area again. He measured 14 cm just as he did on the XL-Tek, marked the reference and re-set the machine for a "sensory" nerve. He labeled it, as he did on the XL-Tek: "median wrist" and "right side". It was set for a "sensory right median wrist". He reapplied a small amount of gel for conduction and started at around 10 (milliamps). It displayed on the screen just as it did for the XL-Tek. He "super-maximalized" it before he saved the results. He testified that it is in "real time", in that you can see it as you are doing it just like on the XL-Tek machine.

Mr. Ross testified that he performed the exact same test on the Brevio® that he had performed on the left hand on the XL-Tek machine. Petitioners' Exhibit No. 13 is a printout of the Brevio® test that Mr. Ross performed on himself the day prior to hearing.

The printouts from the hearing demonstrations were admitted as Petitioners' Exhibit No. 14 (XL-Tek) and Petitioners' Exhibit No. 15 (Brevio®).

On cross-examination, Mr. Ross testified that Triad Diagnostics is a participating provider with Respondent. He acknowledged that as a participating provider Triad Diagnostics has agreed to follow Respondent's documentation guidelines and the participation agreement. He understands that Respondent has established what is and is not payable for nerve conduction studies. He agreed that one of the ways that Respondent's policy is communicated to providers is through the *Record* publication. He was aware of the *Record* article on July 1, 2007. He agrees that the article details the nomenclature for code "S-3905". [Pet. Exh. 3, p 8]. He is positive that this procedure code does not represent what was done with the Brevio® machine. The Brevio® is a table-top device, not a "hand-held" device.

Regarding "super-maximalizing" the stimulation to the nerve, Mr. Ross testified that he starts at low stimulation. He stated that when you start to see the lines, then you know that you are over the nerve. As he increases it, the wave gets bigger. When the wave stays the same, you have "super-maximalized" the stimulation. Then you can determine if the nerve is or is not diseased.

Mr. Ross testified that around 2006 he first started using the Brevio® machine, which was bought new at that time. The company that makes the Brevio® is NeuMed out of New Jersey. [Pet. Exh. 10]. The technology for the device dates back to the 1980's. The Brevio differs from a hand-held device, such as the NC-Stat by Neuro-Metrix with technology that dates back to the 1990's, because it sits on a table. Also, the NC-Stat device is much lighter and about half the size of the Brevio®, and has pre-formed measurements for electrodes on a person's extremities. With the NC-Stat device, the technician pushes a button and everything that Mr. Ross did in his demonstration is done automatically, in contrast with the Brevio® that is "technician dependent". Both the NC-Stat and the Brevio® devices are battery operated; they are not plugged into an electrical outlet.

Mr. Ross testified that the big difference between the two devices is that you cannot have real-time results displayed on the NC-Stat. With the Brevio®, the results are displayed in real time instantly. The NC-Stat has to be loaded into a modem that is hooked into a telephone line, the telephone dials a number where it is read, and then the report is faxed back to the physician. He does not know whether a hand-held or table-top device is used more in the medical profession.

Mr. Ross testified that between the XL-Tek and the Brevio, the report for the XL-Tek is a little bit bigger and the XL-Tek does EMGs (a needle into the muscle that the nerve

interfaces). A licensed physician performs EMGs, although the State of Michigan does allow a licensed physician's assistant to perform EMGs under a physician's supervision. Triad Diagnostic technicians do not perform EMGs and do not have medical licensure (other than Mr. Ross as a physician's assistant). The Triad Diagnostics technicians have training through a national company. Mr. Ross is a licensed physician's assistant whose supervising physician is Harvey Sabbota, D.O. Dr. Sabbota does not work on-site at the Triad Diagnostics office.

Mr. Ross testified that all of Triad Diagnostics' testing is done at a physician's office, where the patient's own physician is on-site and is the supervising physician at that point. Triad Diagnostics takes its instrumentation to the physician's office. Triad Diagnostics is licensed by Medicare as an independent diagnostic testing facility with mobile capacity.

Triad Diagnostics is currently using the XL-Tek device, which is capable of performing EMGs. There are multiple different tests that do not require EMGs with a nerve conduction study. If a physician thinks it is necessary, there can be a referral for an EMG to be performed by a neurologist. The XL-Tek device has not been denied as a covered service by Respondent.

Testimony of Constance Blachut

Constance Blachut was called by Respondent to testify. Ms. Blachut stated that she is the manager of the Utilization Review unit within Blue Cross Blue Shield of Michigan, Respondent, that handles professional audits. In this matter, there was a field or complex audit conducted of Triad Diagnostics, and a desk audit conducted of the other (non-Triad) Petitioners. In a field audit, Ms. Blachut's unit auditors go out to an office where they obtain copies of medical records and look at equipment. In a desk audit, there is strictly a claims review by the auditors.

For the field audit of Triad Diagnostics, Ms. Blachut's unit obtained copies of medical records. The auditors came up with the "logic" that a billing for a nerve conduction procedure code without an EMG was likely to be an "automated" test. They excluded neurologists and physiatrists from their review. They sent out a letter which said it appears that an audited test was an automated nerve conduction study, but also said that if you disagree you can demonstrate on appeal that a different device had been used. Following this letter, a couple of providers came forward, but not the Petitioners in this case.

Ms. Blachut stated that Respondent communicated to providers that it did not pay for automated nerve conduction through the *Record* articles and on Respondent's website, Web-DENIS, as well as through policies that become part of the providers' contracts. The July 2007 *Record* article informed providers that Respondent would not pay for an automated nerve test. If "code S3905" had been billed by the providers, it would have been rejected. The bills submitted under "code 95900" were paid.

On cross-examination, Ms. Blachut testified that Respondent expects providers to look at the *Record* articles and online at Web-DENIS, and to call their provider consultants if they have any questions. Providers can also bring up code definitions and the policy on Web-DENIS. It is also in the CPT Encoder for verification. Plus, the providers could look up the codes that were billed on CPT and Web-DENIS to see if they applied. If the providers did not think the S-code applied, they should have billed for a non-specific code and there would have been a review of the record and a determination then made.

Ms. Blachut testified that there are a number of nerve conduction codes like any other codes. It is a requirement for the providers and federal guidelines in HIPA to find the most accurate code. There are a lot of codes, but that is why there are certified coders, professional consultants with Blue Cross, and software that can help providers.

Ms. Blachut testified that for purposes of the auditors' logic or algorithm, the definition of "automated" is described in Respondent's medical policy. To determine what machines would be considered "automated", they asked their medical consultants who are neurologists and experts in the treatment of nerves. She knows that two of their medical consultants said that they do not use "automated" devices to conduct nerve conduction tests, because they use conventional devices.

To Ms. Blachut's knowledge, the only other device besides the NC-Stat and the Brevio® that was determined by the medical consultants to be automated was the "Neuro-Wave," which was billed the same as the device in these audits and the doctors made the same arguments.

The logic or algorithm by the auditors was based on Respondent's audit experience and the advice of its medical consultants. It is the job of Ms. Blachut's unit to look for billing errors, but they always give providers the option to appeal if they get it wrong. Sometimes the claim was billed wrong. Ms. Blachut thinks that on a couple of appeals there was a determination that EMGs were subsequently done, and in that instance the denial decision would have been reversed.

When Petitioners appealed the initial letter, Respondent requested the name of the device, some information on the device, and a couple sample patient records to review with their medical consultants. The auditors asked for the records because they were trying to determine or prove the device that was used. The matter of EMGs was just an "indicator" to the auditors that the providers were likely doing automated nerve conduction studies. Respondent did not take money back for EMGs. Ms. Blachut testified that the "EMG had nothing to do with the actual demand"; it was just an "indicator" or "selection criteria" that it "probably was" an automated nerve conduction study. They were not questioning or denying care regarding EMGs.

Ms. Blachut testified that there were some cases where a nerve conduction study was done using a conventional device without an EMG having been performed, and Respondent reversed its decision. Respondent's determination did not turn on whether the machine could do an EMG, but rather if you did not do an EMG it was likely that

when you billed for a nerve conduction study that it was automated. It is possible that the nerve conduction study was not automated, and if so, prove it. Going forward, Ms. Blachut did not care about EMGs; it "all centered on the nerve conduction". Ms. Blachut testified that an EMG is "not material," rather "what's material is how did you do your nerve conduction". The auditors did not include neurologists in their audits because neurologists almost always used conventional devices.

Ms. Blachut stated that their auditors are not qualified to evaluate if a device is automated or not. Their medical consultants say if a device falls in the automated or the conventional category, and then they follow their policy.

Ms. Blachut does not know if any of the approved machines have any automated features. She thinks Petitioners' counsel had requested from her a list of machines that were considered "conventional". They were talking about the actual device, not features on a piece of equipment. If a device's user manual indicates that it is "automated", she would have to contact their medical consultants on whether the device would then be considered automated. The term "automated" is defined in Respondent's medical policy and is more of a clinical, professional physician's determination. It is "not a point of law", but "how it is approached by clinicians."

Ms. Blachut testified that none of the denials in the audits were made based on medical necessity. If an audit had been done and a denial letter sent out, and then a provider brought in an EMG report and the device used had been the Brevio®, Respondent would still have asked for a refund. All of the providers had appeal rights, and an opportunity to bring in additional information to substantiate whether a device was conventional or experimental. She handled hundreds of appeals with such additional information.

The codes that were used, being "95900, 95903 and 95904", were not correct. Those codes are for doing the test and interpretation. There is a specific definition for these codes in the CPT. There is a determination as to the amount of resources in doing the procedure. They are tests done on a "conventional" nerve conduction study device.

To Ms. Blachut's understanding, a "conventional" device usually requires more interaction of the person performing the test. There is usually more interpretation by the physician. The technicians often require more training to do the test. Her understanding is that most "automated" devices are hand-held, but she does not know if that it is exclusively so. She relies upon the doctors' judgment as to whether a device is "handheld" or "table-top", but that characteristic is not a deciding factor for Respondent's approval of the device.

Ms. Blachut testified that Respondent asked for information in the audit on the training of the technician who performed the nerve conduction study. Some of the approved studies have been done by technicians under the supervision of a physician in an office. The doctors have explained to her that sometimes they want to adjust the intensity in

the study, depending upon the specific nerves being tested. She believes that the XL-Tek is a device that has been approved by Respondent.

Ms. Blachut testified that she knows that the NC-Stat test results are not immediate, but she does not know whether that is an exclusive deciding factor for purposes of approval. The doctors she has spoken to said that not having immediate results makes the NC-Stat "even more automated", if that is possible. She thinks that some automated devices have a feature for printing out test results, and others do not.

Testimony of Frank Judge, Jr., M.D.

Frank Judge, Jr., M.D. was called by Respondent to testify and was found qualified as an expert in neurological medicine in the state of Michigan. Dr. Judge testified that he attended medical school at the Municipal University of Amsterdam. He did his internship after that at the Geisinger Medical Center in Pennsylvania. He came to the University of Michigan Medical School and did his residency in the Department of Neurology. He then went into the Air Force for two years and was the chief of neurology at the Shefford Air Force Base during the Vietnam crisis. After finishing that, he returned to the University of Michigan for a fellowship in Electroencephalogy. After completing what was necessary for board certification in Electroencephalogy, he worked at the Wayne County General Hospital as head of the neurology department for three years or so. He then went into private practice at the St. Joseph Mercy Hospital in Ann Arbor. He has been on the staff of the Department of Neurology at the University of Michigan for about 35 years. He is a practicing neurologist. He is currently licensed as a physician in the state of Michigan and his license has not been disciplined.

Dr. Judge testified that he has had specific training with respect to the performance of the technical component of nerve conduction studies. He has not used the machines at issue in this case, but he has used several different nerve conduction study machines over the years. With respect to the automation and computerization of machines, initially the machines were much simpler and had limited scopes and did not have the ability that they do now. Over the years, the machines have improved greatly in the display of wave forms and the calculation aspects. He has not designed or created any of the machines. Over the years as a board-certified neurologist, he has done EMGs and nerve conduction studies as part of a neurologist's core abilities.

Dr. Judge stated that the technical advances of the nerve conduction study machines have been great. He would describe an "automated" system as something that requires little human input. The machine does the testing and generates a report, as opposed to a traditional EMG and conduction times done by a highly trained physician who is usually a physiatrist or a neurologist. They sometimes use a trained EMG technician who does the conduction test, but a physician is right there for direct supervision at the technician's elbow or across the hall if there is a question or problem. After the test is done, the physician looks at the wave forms and the values both on a computer screen (that is much larger and with much better resolution than is on the machines shown in

the demonstration at hearing) and a printout and sees if there is any reason that the test needs to be changed or redone or if they need to do different sites of stimulation.

Dr. Judge testified that in the traditional way, a physician begins by taking a history from the patient on the symptoms, how long the patient has had them and where they have occurred, and tries to develop an idea of what is wrong, i.e. a differential diagnosis. After the history taking, a physician does a neurological examination on the patient, examining the reflexes, sensation and strength of the muscles particularly in the area complained of by the patient. After the physician modifies the differential diagnosis following the physical examination, the physician then proceeds to the nerve conduction studies to test the nerves based on what was formulated in the differential diagnosis.

Dr. Judge testified that after the nerve conduction study, 95% or 98% of the time, an EMG (electromyogram) is done, in which a needle is inserted into the different muscles looking for abnormalities, in order to diagnose muscle disease, diseases of the junction between the nerve and the muscle (as in Myasthenia gravis), or diseases of the nerve.

Dr. Judge testified that with carpal tunnel conditions, the problem with simply doing motor conduction tests is that you cannot judge the severity of the disease. He thinks it is inseparable and an essential part in looking at carpal tunnel to do an EMG before any surgical release of the muscles, because carpal tunnel is very common but there are other conditions that are possible.

With diabetic neuropathy, it is a different question. In 50% of neuropathy patients that present without etiology to a neurologist, the patients are diabetic. You do not first do an EMG or nerve conduction test, but rather a diabetes test. If the diabetes test is positive, you might do one other blood test (such as for B-12) to test for a very rare combination. The value of conduction times with diabetic neuropathy would be uncommon and have to be some very unusual presentation. You do not take diabetic patients and just routinely check for nerve conduction times. It would mean nothing as far as changing treatment. You treat the diabetes condition, for the neuropathy.

Regarding the July 1, 2007 *Record* article and the July 1, 2008 medical policy by Respondent related to automated devices, Dr. Judge did not have any input. The policy was made before he got involved in this case. He has never used the XL-Tek and Brevio® machines shown in the demonstration at the hearing. He was not involved in reviewing medical records or making any denials for these audits.

In the demonstration of the machines at hearing which Dr. Judge observed, the technician measured out and placed electrodes in certain areas, then punched a screen, stimulated the hand and then generated a report. In the demonstration of the XL-Tek and the Brevio® machines at the hearing, the testing done was very similar. The placement of electrodes was exact and precise according to what the protocol is. The machines are basically very similar in the display of the wave form and the various F-waves, the latencies and so forth. He found both machines to be automated because the only human input in the demonstration was the placement and measurement of the

electrodes and then the set up of the computer program. With conventional nerve conduction studies, the trained EMG technician has a minimum of six months of training. The technique between the conventional and automated tests is similar, but the only drawback is the fixed, routine testing on the automated devices which takes away the ability of an experienced EMG technician or physician with training in this area to vary the test according to the differential diagnosis, in order to either confirm or deny the diagnosis.

Dr. Judge stated that he sits on credentialing committees for Priority Health and the St. Joseph Mercy Hospital System. The committees credential providers to do procedures, depending upon whether the providers are adequately trained for procedures. Someone with very inadequate training could do some physical measurements, but not be permitted to practice and do the tests in the hospital.

Dr. Judge testified that he has not taken a poll of the neurological community, but having seen the demonstration of the machines in the hearing it clearly looked to him like the Brevio® is an automated procedure. He thinks that both the Brevio® and the XL-Tek machines are automated. For his opinion summary shown in Respondent's Exhibit No. 5, he reviewed the websites and the brochures advertising what the instruments were capable of and what their indications were. He reached a conclusion that the interpretation was being done by a computer of the wave forms and latencies. There was no interpretation on the printout reports.

FINDINGS OF FACT

Based on the entire record in this matter, including the witness testimony and admitted exhibits, the following findings of fact are established:

1. Petitioner Triad Diagnostics is a limited liability corporation located in Novi, Michigan, which was incorporated in 2002. Robert R. Ross is a licensed physician's assistant (P.A.) who is a co-owner of Triad Diagnostics. Harvey Sabbota, D.O. is Mr. Ross' supervising physician.
2. Mr. Ross has received training in conducting nerve conduction studies through his work experience with physicians, attending courses in the Department of Neurology at the University of Michigan, and the Larry Head Institute.
3. In turn, Mr. Ross has provided a six-week training course to persons (who are not licensed health professionals) to become technicians who then perform nerve conduction studies on behalf of Triad Diagnostics. These technicians have also received training by a personal trainer from the Larry Head Institute before becoming certified.

4. Mr. Ross and other technicians from Triad Diagnostics perform nerve conduction studies on patients only at physician's offices. The physician present in the office at the time of the study acts as the supervisor for the study.
5. Addendum H to the applicable participation agreement between the insurer Blue Cross Blue Shield of Michigan, Respondent, and Petitioners allows Respondent the right to recover amounts paid for services that do not meet applicable benefit criteria or are non-covered services, or which are not medically necessary as determined by Respondent under Addendum A. [Pet. Exh. 6, p 24].
6. Under Addendum A to the participation agreement, for purposes of payment by Respondent, "medical necessity" means that a service is in accordance with "generally accepted standards" of medical practice, based on "scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of physicians practicing in relevant clinical areas and any other relevant factors." [Pet. Exh. 6, p 12].
7. Addendum F to the participation agreement states that a practitioner may bill a member for a service determined to be "medically unnecessary or experimental" only if the member specifically agrees in writing in advance of receiving services, that the member acknowledges that Respondent will not make payment for the experimental service, and that the member assumes financial responsibility for the service. [Pet. Exh. 6, p 22].
8. In March 2002, Respondent published an article in its newsletter to providers, *The Record*, which was likely reasonably intended to give notice that "surface electromyography (EMG)" was not a covered service. [Resp. Exh. 3].
9. At times relevant to the audit period, Respondent's medical policy stated that the effectiveness and clinical utility of "surface electromyography (SEMG)" was an "office-based, non-invasive procedure . . . performed using one or more electrodes that are placed on the skin surface." The policy found that surface electromyography was unacceptable, inconclusive or inadequate as a clinical tool. It concluded that surface electromyography is considered "experimental/investigational." [Resp. Exh. 3 & 6, pp 1-2].

10. Respondent's medical policy on the lack of medical necessity of "surface electromyography" is likely supported by medical consultant opinion, a March 2006 position statement by the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM), some medical literature, the position of the State of Washington, and some competing insurers. [Resp. Exh. 3, 5, 8, 12 & 13].
11. In June 2007, Respondent published an article in *The Record*, which was likely reasonably intended to give notice to providers of an added procedure code "S3905," effective July 1, 2007, that was to be used for "non-invasive electrodiagnostic testing with automatic computerized hand-held device to stimulate and measure neuromuscular signals in diagnosing and evaluating systemic and entrapment neuropathies." This notice indicated that the testing as described was covered for "FEP" or the federal employee program only. [Resp. Exh. 3, p 8]. (Emphasis supplied).
12. The June 2007 *Record* article did not define the term "automated" or specifically identify the Brevio®, NC-Stat® or any other particular device as being intended for procedure code S3905. Respondent has reasonably contended that it is impractical for an insurer to name all covered devices in its medical policy. [Resp. Exh. 3, p 8; Response to Petitioners' Motion for Summary Judgment]. In 2009 and 2010, Respondent conducted post-payment review desk audits of payments made to Petitioners for the time period of July 1, 2008 through June 30, 2009. The audited payments were for nerve conduction studies that had been performed.
13. On October 27, 2009, Respondent initially requested a refund from Triad Diagnostics in the amount of \$104,617.58. On April 19, 2010, a managerial level conference was conducted with Triad Diagnostics, and Respondent maintained its refund request. [Resp. Exh. 1].
14. Respondent further expanded the scope of its audits to include physicians who were billing for nerve conduction studies without an electromyography (EMG).
15. Following the audit, Respondent maintained that Petitioner Triad Diagnostics had improperly billed for the "technical" component of automated nerve conduction studies that were performed at the physicians' offices, and that the other Petitioner providers had improperly billed for the "professional" component of the studies.

16. Per Petitioners' counsel statement at hearing, the only nerve conduction study device that remains at issue in this matter is the Brevio® by Neurotron Medical, Inc. Petitioner's counsel indicated that the NC-Stat device addressed in the Review and Determination was not billed by Petitioners (even though the Review and Determination, page 3, reflects that Petitioner Grunberger used both devices).
17. Respondent made a determination that a service using the Brevio® device should be billed under the code for "noninvasive electrodiagnostic testing", which is a type of service not covered except for a federal employee program at times relevant. On December 17, 2009, Connie Blachut, Manager of Respondent's Utilization Review, wrote as follows to Petitioners' counsel:

"It is BCBSM'S determination that the procedure rendered by the Brevio® device is the HCPCS code S3905-noninvasive electrodiagnostic testing with automatic computerized hand-held device to stimulate and measure neuromuscular signals in diagnosing and evaluating systemic and entrapment neuropathies. The FDA description of the Brevio device accurately matches the description of code S3905. BCBSM's payment policy does not allow for payment of code S3905." [Resp. Exh. 1]. (Emphasis supplied).

18. The record contains a description of the Brevio® device in part as follows:

"The BREVIO is a battery powered (4 AA batteries) hand held device that is utilized to perform motor and sensory nerve conduction testing on peripheral nerves in a clinical setting. It consists primarily of two units, a handheld process with LCD screen and a stimulator. * * *

"The BREVIO automatically picks out the latency and amplitude of waveforms presented to determine the values associated with them. The automatically chosen values may be manually adjusted by the user should the user feel the necessity to manually make such a change.

"The BREVIO has memory storage of 28 waveforms for later viewing and printing of the test results." [Resp. Exh. 1 "501(k) Summary"]. (Emphasis supplied).

19. After Petitioners sought reconsideration of Respondent's audit findings, Respondent stated in a letter of May 6, 2010 that the NC-Stat® and

Brevio® devices are "portable nerve conduction test devices designed to be used at the point of care. They are meant to be used as adjunct to, and not a replacement for, conventional electrodiagnostic measurements. Although studies have shown the correlation of automated nerve conduction tests with standard testing, the effectiveness and clinical utility have not been established. Therefore, while they may be safe, the use of automated nerve conduction studies is considered experimental or investigational." [5/6/10 letter in Pet. Exh. 2]. (Emphasis supplied).

20. The Brevio® device has some features that are likely "automated", in the sense that they do not require human input. For example, the Brevio® automatically picks out the latency and the amplitude of waveforms, and has automatically chosen values initially. [Pet. Exh. 1].
21. The Brevio® also has some features that are not likely "automated", in the sense that they do require human input. For example, it allows for the manual adjustment of electrodes by a technician and the manual measurement of distances on a patient's body, unlike the NC-Stat. It is not limited to the testing of nerves in pre-set nerve settings. Both directions of conduction are available, unlike other devices that have been considered automated. It does not use internal software correction factors like some other devices, in an effort to accurately acquire test data. [Pet. Exh. 1, 8 & 10; Resp. Exh. 13].
22. The Brevio® device produces real-time test results that appear on a screen for purposes of the adjustment of voltage and other factors as the study is conducted, which Mr. Ross credibly testified is an important difference between the Brevio® and the NC-Stat. [Pet. Exh. 1 & 10].
23. The Brevio® is not likely meant to be "hand-held" and weighs more than the NC-Stat. It is likely designed to be used on a table top next to a patient.
24. After observing the function of the Brevio® at hearing, however, Respondent's expert witness, neurologist Frank Judge, M.D., credibly testified that the only human input he saw was the placement and measurement of the electrodes and the set up of the computer program, and that the actual interpretation of wave forms and latencies was done by computer.
25. Dr. Judge provided a written opinion to Respondent that the Brevio and the XL Tek (Neuromax) devices are "both automated devices in that once the electrodes are placed, the process of generation of a report and interpretation of the results is done by a computer without the input

of a human.” [Resp. Exh. 5]. (Emphasis supplied).

26. Petitioners contend that the question of “interpretation” is not at issue for purposes of refunds for the “technical” component of the test, but based on Dr. Judge’s credible testimony it reasonably appears that how a test interpretation is done, whether by trained physician or solely by computer, is integral to the device’s efficacy as a clinical tool and thus, medical necessity. [Resp. Exh. 6].
27. Partially automated devices that perform surface electromyography, such as the Brevio® and the XL-Tek, may be adjunct to but do not likely substitute for conventional nerve conduction studies performed by a physician or technician under the direct supervision of a physician trained in the area of neurological medicine, as credibly described by Dr. Judge at the hearing. While computers are likely used in the course of conventional nerve conduction studies, they do not likely substitute for medical judgment per Dr. Judge’s credible testimony.
28. Some of the denial letters following post-payment audits sent out by Respondent referenced the lack of a procedure code for needle electromyography (EMG) and stated that “[n]erve conduction studies (NCS) that are performed without the needle EMG are considered to be automated nerve conduction studies.” [3/26/10 letter in Pet. Exh. 2].
29. Mr. Ross acknowledged in his testimony at hearing that an EMG cannot be performed with the Brevio® device, but that an EMG can be performed with an XL-Tek and other approved devices.
30. In her hearing testimony, however, Ms. Blachut clarified that the question of EMGs was only used by Respondent as an audit “indicator” or “selection criteria”, and was not actually the basis for approval or denial of a nerve conduction study device. She acknowledged that there have been nerve conduction studies approved by Respondent that did not have corresponding EMGs performed.
31. Respondent also denied reconsideration at the informal managerial conference level based in part on the fact that there were no peer-review articles for the Brevio®, even though Petitioners likely provided a link to a list of peer-review articles concerning the device. [Pet. Exh. 7; Resp. Exh. 1]
32. Mr. Ross acknowledged in his testimony at hearing that the Brevio® conducts a “surface EMG”. Based on the March 2002 and June 2007 *Record* articles, Petitioners were likely on notice during the relevant audit period that Respondent considered surface electromyography

and the devices in question to be investigational/experimental. [Resp. Exh. 3 & 6].

33. Following the audits, the managerial level conference level and the Review and Determination by the Commissioner's Designee, Respondent maintained a request for refunds from Petitioners in the total refund amount of \$205,139.91. No portion of the amount is based on statistical projection. [Resp. Exh. 1].
34. During the audit period, Petitioners billed for their use of the Brevio® device under CPT codes "95900, 95903 and 95904", which were likely the procedures codes for conventional nerve conduction studies.
35. Procedure code 95900 is described as for "nerve conduction, amplitude and latency/velocity study, each nerve". Procedure code 95904 is for "nerve conduction, amplitude and latency/velocity study, with F-wave study". Procedure code 95904 is for "nerve conduction, amplitude and latency/velocity study, each nerve; sensory." The code descriptions do not specify the instruments or devices that must be used for the approved nerve conduction studies.
36. Petitioners have not shown that they contacted Respondent during the audit period of July 1, 2008 to June 30, 2009, to check on whether the Brevio® device was approved, or that Respondent misrepresented its medical policy on the device.
37. On July 8, 2010, after the audit period had ended, Petitioners' attorney contacted Ms. Blachut about approved devices. At that time, Respondent indicated that the NeuroMax XL Tek device had been reviewed and approved as a conventional or traditional device for nerve conduction. Ms. Blachut stated that "This is likely not complete, but only reflects those devices that providers sent information in to us as a result of our audit." [Pet. Exh. 9].
38. The user manual for the XL-Tek shows that it is a device that has some automated features that can be adapted by the user. [Pet. Exh. 8, pp 9, 14 & 46]. The specific circumstances of claims for which the XL-Tek has been approved are not known on this record, however.
39. Between July and November 2010, Petitioners filed requests for review in the Office of Financial and Insurance Regulation regarding its dispute with Respondent.

40. On February 16, 2011, a meeting of the parties was conducted in the Office of Financial and Insurance Regulation by the Commissioner's Designee, Susan M. Scarane.
41. On May 25, 2011, the Commissioner's Designee issued a Review and Determination, which concluded that Respondent had not violated the Nonprofit Act, *supra*, when it sought refunds from Petitioners totaling \$205,139.91. [5/25/11 Review and Determination, p 20].
42. On July 19, 2011, Petitioners submitted a Request for Contested Case Hearing to the Office of Financial and Insurance Regulation seeking reversal of the Review and Determination, in which it alleged that Respondent had violated Sections 402(1)(a-f) and (l-m) of the Nonprofit Act, *supra*, and that Respondent was not entitled to any of the amounts claimed as overpayment following the post-payment audits.
43. On July 27, 2011, Special Deputy Commissioner Randall S. Gregg issued an Order Referring Complaint for Hearing and Order to Respond. The attached Complaint states that a hearing would be "held to determine if the factual allegations are true." [Complaint, p 1].

CONCLUSIONS OF LAW

Petitioners, as the complaining party, have the burden of proof to show by a preponderance of the evidence that Respondent has violated the Nonprofit Act, *supra*, as alleged in the Complaint and Request for Contested Case Hearing, and that Respondent is not entitled to the amounts claimed as overpayment as a result of the post-payment audits. See, *American Way Service Corporation v Commissioner of Insurance*, 113 Mich App 423; 317 NW2d 870 (1982).

In essence, Petitioners contend that Respondent did not give adequate notice that the Brevio® device was considered experimental/investigational and not covered, and that Respondent has not acted reasonably in seeking the refund of payments made for services rendered with the device during the audit period.²

² Petitioners also contend that they were not copied on documents containing opinions of anonymous medical consultants that were submitted by Respondent to the Office of Financial and Insurance Regulation following the Commissioner's Designee's meeting with the parties, and that they were not afforded an opportunity to respond to such documents prior to issuance of the Review and Determination. Respondent indicates that it provided the documents in response to the Commissioner's Designee post-meeting request. Rule 105(3) clearly requires such meetings to be conducted "in a manner which allows the disputing parties to present relevant information to substantiate their positions." 1996 AACR, R 550.105(3). As the present proceeding is a *de novo* hearing, however, the meeting process before the Commissioner's Designee does not bear on the outcome here.

Based on the above findings of fact, it is concluded that Petitioners have not met their burden of proof. Rather, a preponderance of record evidence shows that Respondent likely gave Petitioners reasonable notice prior to the audit period that any services using a device such as the Brevio® for surface electromyography would be considered experimental/investigational and not covered. While Petitioners have shown that Respondent likely gave more than one reason to Petitioners for seeking refunds following its post-payment audits, it has not shown that Respondent deviated from its established medical policy on surface electromyography in denying services performed with the Brevio® or that it acted unreasonably in seeking refunds.

As to the alleged violations of the Nonprofit Act, the record evidence does not show that Respondent likely misrepresented pertinent facts or certificate provisions; failed to acknowledge promptly or act reasonably upon communications with respect to a claim; failed to adopt and implement reasonable standards for the prompt investigation of a claim; refused to pay claims without conducting a reasonable investigation based upon available information; failed to affirm or deny coverage of a claim within a reasonable time after a claim had been received; failed to attempt in good faith to make a prompt, fair, and equitable settlement of a claim for which liability had become reasonably clear; failed to promptly provide a reasonable explanation of the basis for denial of a claim or for the offer of a compromise settlement; or failed to promptly settle a claim where liability had become reasonably clear. Therefore, Petitioners have not proven a violation of Section 402(1)(a)-(f) & (l)-(m) of the Nonprofit Act by a preponderance of the evidence.

PROPOSED DECISION

Based on the above findings of fact and conclusions of law, the undersigned Administrative Law Judge proposes that the Commissioner issue a Final Order that finds no violation of the Nonprofit Act by Respondent as alleged, and that denies Petitioners' request for a ruling that Respondent is not entitled to seek the refunds in question.

EXCEPTIONS

Any Exceptions to this Proposal for Decision should be filed in writing with the Office of Financial and Insurance Regulation, Division of Insurance, Attention: Dawn Kobus, P.O. Box 30220, Lansing, Michigan 48909, within twenty (20) days of issuance of this Proposal for Decision. An opposing party may file a response within ten (10) days after exceptions are filed.



Lauren G. Van Steel
Administrative Law Judge